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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,272	07/17/2003	Illana Gozes	015280-291300US	3514
20350	7590	03/31/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER
			1647	
DATE MAILED: 03/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,272

Applicant(s)

GOZES ET AL.

Examiner

Marianne P. Allen

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/187,330.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 3-4, 6, and 56-58, in the reply filed on 12/21/05 is acknowledged.

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/21/05.

Priority

Applicant is requested to update the priority applications listed in the first sentence of the specification including their status as well as the relationship among the named applications.

Claim Rejections - 35 USC § 112

Claims 3-4, 6, and 56-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement and written description rejection.

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Claim 57 does not indicate that the host cell is isolated. Page 32 of the specification does not disclose nor contemplate transgenic animals or plants. Only isolated host cells that can be cultured to produce the protein are disclosed. As such, this new claim is considered to embrace new matter.

Claim 3 recites “an ADNF gene having a nucleic acid sequence comprising SEQ ID NO: 2, SEQ ID NO: 56, or SEQ ID NO: 58.” The specification does not disclose any ADNF gene or genomic sequences. The structure of these genomic sequences is not known. It is noted that SEQ ID NOS: 2, 56, and 58 are cDNA sequences from human. (See specification page 4-5, bridging paragraph.)

Claim 3 and dependent claims are directed to isolated nucleic acids that encode an ADNF III polypeptide. Page 14 defines “ADNF III polypeptide” in such broad terms that it cannot be determined what structure and/or function these polypeptides must possess and as such, what isolated nucleic acids would encode them. As claimed, this isolated nucleic acid must hybridize to an undisclosed ADNF III gene. The claims can be viewed similarly to those in Ex parte Maizel, 27 USPQ2d 1662, 1665. The Board of Patent Appeals and Interferences held that claims drawn to DNA sequences encoding biologically equivalent proteins (i.e. DNA encoding proteins that do not have a defined amino acid sequence) are not enabled when the specification discloses a single specific DNA sequence known to the inventor having the biological limitations. The disclosure was held not to be commensurate in scope with the breadth of such claims because DNA sequences encoding biologically equivalent proteins covers any DNA sequence encoding a protein that achieves the stated biological result. For similar reasons, the instant disclosure is not commensurate in scope with the breadth of the claims. With the exception of the particularly

disclosed nucleic acid sequences encoding ADNF III polypeptides, the specification fails to define the structural features of the claimed isolated nucleic acids encompassed by the claims sufficient to meet the requirement of written description.

The specification specifically discloses:

SEQ ID NO: 4 mouse cDNA of 2421 nucleotides (encodes SEQ ID NO: 3, 806 amino acids)
SEQ ID NO: 54 mouse cDNA of 2487 nucleotides (encodes SEQ ID NO: 55, 828 amino acids)
SEQ ID NO: 2 human cDNA of 4874 nucleotides (encodes SEQ ID NO: 1, 1000 amino acids)
SEQ ID NO: 56 human cDNA of 2181 nucleotides (encodes SEQ ID NO: 57, 726 amino acids)
SEQ ID NO: 58 human cDNA of 4193 nucleotides (encodes SEQ ID NO: 59, 874 amino acids)

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.)

Except as outlined above, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acids and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See at least Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, and University of California v. Eli Lilly and Co., 43 USPQ2d 1398.

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The specification disclosure is not sufficient to support the breadth of isolated nucleic acid sequences embraced by the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "encodes an ADNF polypeptide comprising...SEQ ID NO: 6." This language is not consistent with claim 3 which recites "encodes an ADNF III polypeptide." Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Nagase et al. (DNA Research, 5(5):277-286, October 30, 1998).

At least SEQ ID NOS: 54-59 are not disclosed in parent application PCT/US98/02485 (now WO 98/35042). As such, applicant is entitled to benefit of the 09/187,330 parent filing date (11/6/98) for claims 3-4, 6, and 56-58 and Nagase et al. is valid prior art.

Nagase et al. discloses gene number KIAA 0784 (Genbank Accession No. AB018327). This is a 4282 nucleotide cDNA with an open reading frame of 1073 amino acids.

This sequence has 99% similarity to both SEQ ID NOS: 56 and 58. It would inherently encode an ADNF III polypeptide meeting the limitations of claim 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase et al.

Nagase et al. is applied as above. The reference does not disclose expression vectors, host cells containing them, or methods of producing proteins.

It would have been obvious to produce an expression vector, host cell contain^{ing} the expression vector, and produce the protein encoded by gene number KIAA 0784 (Genbank Accession No. AB018327). This is a 4282 nucleotide cDNA with an open reading frame of 1073 amino acids. One would have been motivated to do in order to further characterize this novel cDNA. The disclosure of Nagase et al. demonstrates that characterization of unknown proteins encoded by novel cDNAs would have been of interest. Production of expression vectors containing novel cDNA sequences encoding proteins, host cells containing them, and recombinant methods of producing the encoded proteins would have been well known to those of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Marianne P. Allen

Marianne P. Allen
Primary Examiner
Art Unit 1647

3/30/06

mpa